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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,691	02/07/2002	Lucio Giambattista	P-5023	3218

27305 7590 10/21/2002

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

Office Action Summary

Application No.

10/072,691

Applicant(s)

GIAMBATTISTA ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply.

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 6. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-4, 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S Patent No.4894055 to Sudnak.

Sudnak teaches a safety shield system for a needle cannula comprising a general tubular clip member having a plurality of spaced laterally projecting fingers 30, a generally tubular reciprocal shield 16 including a first portion surrounding the said clip member (figure 3), a second portion normally surrounding the needle cannula 29 and a plurality of spaced axially extending inwardly opening channel shaped tracks 46 on the inside surface of the shield receiving said laterally projecting resilient fingers of the clip member and guiding said shield axially from a first position wherein said shield 16 second portion surrounds said needle cannula 29 to a second position wherein said needle cannula 29 is exposed, and a spring 40 resiliently biasing said shield axially to normally extend said shield second portion to surround said needle cannula, wherein at least one of said channel shaped tracks 46 includes an opening 42 which receives one of the fingers when said shield 16 is first retracted to said second position and then extended to the first position by the spring and locking the shield in the first position.

The figures 30 include a hook shaped end 36 portion opening towards the first portion of

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the shield and said opening 42 extends through a the wall of the shield receiving the finger hook shaped end portions there through, locking the shield in the first position surrounding the needle cannula.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 5-7, 15-17, 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.4894055 to Sudnák, and further in view of U.S Patent No.6203529 to Gabriel et al.

As mentioned above Sudnak teaches a safety shield system for a needle cannula comprising a general tubular clip member having a plurality of spaced laterally profiting fingers 30, a generally tubular reciprocal shield 16 including a first portion surrounding the said clip member (figure 3), a second portion normally surrounding the needle cannula 29.

Sudnak however does not teach a removable cup shape cap, a needle cannula having two portions, or a clip member with ribs to prevent rotation of the shield relative to the clip member. Gabriel teaches a needle arrangement with a removable cap, a needle with two portions and a clip member with ribs 45 to prevent rotation of the shield relative to the clip member

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Therefore it would have been obvious to one having ordinarily skill in the art at the time the invention was made to have combined these two studies, because according to Gabriel a cap allows for the device to be sterile, the two portions of the needle cannula allows for the device to be used for withdrawn of fluids from a vial as well as injection of the fluid to the patient, hence increasing the function and application of the device. (Col.1, lines 35-50) Furthermore by adding the ribs to the device the needle shield must move laterally only and it prevents the rotational movement of the needle in respect to the shield. Rotational movement of the needle makes it challenging for the patient to administer and use the needle assembly.

3. Claims 8-10 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.4894055 to Sudnak, and further in view of U.S Patent No.6416323 to Grenfell et al.

As mentioned above Sudnak teaches a safety shield system for a needle cannula comprising a general tubular clip member having a plurality of spaced laterally profiting fingers 30, a generally tubular reciprocal shield 16 including a first portion surrounding the said clip member (figure 3), a second portion normally surrounding the needle cannula 29.

Sudnak however does not teach fingers each with a U-Shaped portion. Grenfell teaches a syringe with needle shield having fingers 180 with a U-Shaped portion 178 (figure 9)

Therefore it would have been obvious to one having ordinarily skill in the art at the time the invention was made to have combined these two studies, because

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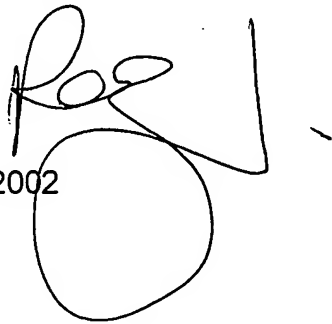
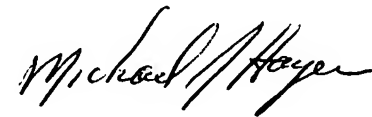
according to Grenfell this type of clip member allows for a better lock on the safety shield hence reducing the risk of accidental needle sticks during use and disposal of the device. (Col. 3, lines 45-50)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG
October 11, 2002

A handwritten signature in black ink, appearing to read 'Roz', with a large, loopy flourish underneath.A handwritten signature in black ink, appearing to read 'Michael J. Hayes', written in a cursive style.

**MICHAEL J. HAYES
PRIMARY EXAMINER**